FDA 510(k) Premarket Notification

K946376 MAXX

CLEARED

Sep 22, 1995
282 days to decision

K946376 · Product code: **HIS** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k946376/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	Dec 14, 1994
Decision date	Sep 22, 1995
Days to decision	282 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Mayer Laboratories**
Location	Oakland, CA, US
Contact	DABID MAYER
510(k) history	16 submissions · 16 cleared · 1987-2001